REMARKS

This Amendment is responsive to the Office Action mailed on June 24, 2008, rejecting all pending claims 18, 32-34, 37 and 39-41. The Office Action was made final even though it was the first Office Action following a request for continued examination that included substantive claim amendments. Reconsideration of the finality of the Office Action is requested for the reasons presented below. By this response claims 18, 32-34 and 41 are amended. Entry of this amendment and reconsideration and allowance of claims 18, 32-34, 37 and 39- 41 are requested.

Finality of Office Action

The June 24, 2008 Office Action was made final, even though it was the first Office Action following a RCE. The stated reason is that the claims are drawn to the same invention claimed in the earlier application, and could have been finally rejected on the grounds and art of record in the next Office Action if they had been entered in the earlier application. The applicant respectfully asserts that the finality of the Office Action is premature, and requests that it be withdrawn.

By the Amendment submitted with the RCE, the claims were amended to characterize the device applied to the heart as being elastic. This amendment distinguished the invention in important and material respects from the grounds of rejection asserted in the earlier Office Action. Substantial reasons supporting the applicant's position were presented in the remarks accompanying the amendment. This amendment therefore would not have been properly finally rejected on the grounds and art of record if it had been entered in the earlier application. Withdrawal of the finality of the Office Action and entry and consideration of this Amendment are requested for these reasons.

§ 112 Rejection

Claims 18, 32-34, 37 and 39-41 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action

asserts that the addition of "elastic" to the claim constitutes new matter. The applicant respectfully disagrees.

Embodiments of the invention that have an elastic jacket are described in the application. For example, paragraph 0019 of the published version of the application incorporates by reference the commonly assigned Alferness U.S. Patent 5,702,343. Column 1, lines 60-63 of U.S. Patent 5,702,343 states that the device can be elastic or non-elastic. The specification therefore supports this claim amendment for at least this reason. Withdrawal of the § 112 rejection is requested accordingly.

§ 103 Rejection

Claims 18, 32-34, 37 and 39-41 stand rejected under 35 U.S.C. §103 as being unpatentable over the Lederman U.S. Patent 6,224,540 in view of the Gordon U.S. Patent 5,336,253. Briefly, the Office Action asserts that it would have been obvious to provide the means of Lederman with electrotherapy means in view of Gordon.

Although not acquiescing with this position, claim 18 is amended by this response to more particularly point out and distinctly claim the applicant's invention, and to better distinguish this invention from the references of record. Specifically, claim 18 is amended to recite a method that includes placing a jacket of compliant, elastic and open cell material around the ventricles of an accessed heart to passively constrain circumferential expansion. The method also includes causing an electrical element to extend through an open cell in the jacket to operatively engage the accessed heart and to couple electrical therapy to the heart. After placing the jacket and causing the engagement of the electrical element, the heart is de-accessed.

This method offers a number of important advantages. The passive constraint therapy provided by the jacket and the ability to apply electrical therapy to the heart are achieved during a single surgical procedure. The combination of these therapies provides enhanced treatment options for patients suffering from heart disease. The open cell nature of the jacket, and the attendant ability of the electrical element to extend through these cells, enables the procedure to be efficiently performed. This enhanced efficacy is achieved with

reduced morbidity and without other undesirable aspects that can be associated with multiple surgical procedures.

A method having these features and advantages is neither taught nor suggested by the prior art of record. To begin with, combining the features in the Lederman and Gordon patents fails to even provide a method having all the features of the applicant's invention. The invention includes placing a compliant and elastic jacket on the heart to passively constrain expansion. The Lederman patent, on the other hand, describes a girdle that is incapable of providing this therapy. Instead, the Lederman patent discloses a girdle (30) made of interlinked "plastic" rings that "are free to move in all directions without restraint, since none are physically connected to each other." (Col. 5, lns. 31-33). The stated purpose of the girdle shown in the Lederman patent is to "limit the maximum diastolic dimension of the heart." (Col. 5, lns. 2-28). Nowhere in the Lederman patent is there any suggestion that the plastic rings themselves or the girdle as a whole are both compliant and elastic. To the contrary, the teachings of the Lederman patent discussed above suggest, if anything, that the plastic rings and girdle are inelastic.

The heart and the physiology of its operation are very complicated. Therapy provided by a compliant and elastic jacket of the type recited in the claims can provide efficacious results on patents with heart disease. The application of therapy of this type is not suggested by the Lederman patent, since this patent does not describe a device having both compliant and elastic characteristics. Contrary to the assertions in the Office Action, the Lederman patent does not provide therapy of the type recited in the applicant's claims.

Another significant difference between the claimed invention and the prior art is the extension of the electrical element through an open cell in the jacket. The Gordon patent discloses a pacing lead system. But there is no suggestion in this patent as to how the pacing lead system could be combined with the device shown in the Lederman patent so the electrical element extended through an open cell. Similarly, the Lederman patent offers no suggestion as to how the device shown therein could be combined with an electrical element to provide electrical therapy, much less the particular recitation of the electrical element extending through an open cell in the device.

The therapy provided by the open cell jacket is considerably different in nature than that provided by the electrical element extending through the jacket cell. Subtle mechanical forces applied by the jacket passively constrain expansion of the heart. The electrical elements, on the other hand, couple electrical signals to the heart for active therapies such as pacing and defibrillation. Extending the electrical element through an open cell in the jacket provides synergies between these two therapies.

The method recited by the claims is not a combination of prior art elements by known methods with no change in their functions. Nor are these recited features combined in a way that is predictable from the prior art. The prior art of record neither teaches nor suggests a cardiac disease treatment method having these features and advantages. Withdrawal of the § 103 rejection and allowance of claims 18, 32-34, 37 and 39- 41 are requested for these reasons.

Respectfully submitted,

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